## REMARKS

Claims 1, 2, and 4-26 are pending in the present application. In the Office Action mailed November 13, 2008, the Examiner rejected claims 1-12 under 35 U.S.C. §101. The Examiner next provisionally rejected claims 1, 13, and 20 on the ground of nonstatutory double patenting over claims 1, 8, and 16 of copending Application No. 10/864,567. Claims 1, 2, 5-9, 13, 16-19, and 24-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger (USP 6,216,025) in view of Takashima (JP363211879). Claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger in view of Bae et al. (US Pub. 2007/0140541), further in view of Takashima. Claims 10-12, 13-15, 20, 21, and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger in view of Bae et al., further in view of Ben-Haim et al. (US Pub. 2002/0065455). Claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger in view of Ben-Haim et al., and further in view of Mass. III (USP 6,181833).

The Examiner rejected claim 1 under 35 U.S.C. §101. In the rejection, the Examiner stated that claim 1 is directed toward nonstatutory subject matter because "the steps recited are purely mental steps." Office Action, 11/13/08, pg. 2. Applicant respectfully disagrees. Claim 1 calls for a method that includes, in part, acquiring a first set of TCT data from a first portion of a measurement surface, determining a second set of TCT data from the first set of TCT data, and reconstructing an image of the imaging object based on the first set and the second set of TCT data. Clearly, actual data is acquired (the first set of TCT data), the data is transformed (the second set of TCT data), and the data is transformed a second time and an image is reconstructed.

To be patent-eligible subject matter, the Federal Circuit recently articulated the machineor-transformation test. See Bilski, 2007-1130, 545 F.3d 943 (Fed. Cir. 2008). Specifically, the Federal Circuit stated that "[t]he machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies §101 either by showing that his claim is tied to a particular machine, or by showing that the claim transforms an article." Id. at 24. The Federal Circuit further stated:

[W]e held one of Abele's dependent claims to be drawn to patent-eligible subject matter where it specified that "said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner." <u>Abele</u>, 684 F.2d at 908-09. This data clearly represented physical and tangible objects, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible.

We further note for clarity that the electronic transformation of the data itself into a visual depiction in <u>Abele</u> was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented. We believe this is faithful to the concern the Supreme Court articulated as the basis for the machine-or-transformation test, namely the prevention of pre-emption of fundamental principles. So long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle. Id. at 26

Clearly, as articulated in Bilski, that called for in claim 1 is patent-eligible. Claim 1 calls for acquiring TCT data and reconstructing an image (e.g. a visual depiction of a physical object) therefrom – which the Federal Circuit stated is "sufficient to render that ... process patent-cligible." And, despite holding that the "visual depiction in <u>Abele</u> was sufficient" and that "the claim was not required to involve any transformation of the underlying physical object that the data represented," claim 1 clearly calls for transformation of data, as well.

Thus, since claim 1 includes TCT data that represents a tangible object and since the TCT data is reconstructed into an image, Applicant believes the rejection of claim 1 under 35 U.S.C. §101 is improper and requests the withdrawal of the rejection thereof, and the claims that depend therefrom.

Claims 1, 13, and 20 were provisionally rejected on the ground of nonstatutory double patenting over claims 1, 8, and 16 of copending Application No. 10/864,567. It is apparent that the Examiner rejected the claims under ¶8.39 of MPEP §804, as the language supporting the rejections resembles the form paragraphs described therein. Compare Office Action, 11/13/08, pg. 3 and MPEP §804, ¶8.39.

However, ¶8.39 of MPEP §804 is reserved for situations where In re Schneller is applicable. In re Schneller, however, includes a specific set of circumstances and is reserved for rejections that include those specific circumstances. The MPEP says:

The decision in In re Schneller did not establish a rule of general application and thus is limited to the particular set of facts set forth in that decision. The court in Schneller cautioned "against the tendency to freeze into rules of general application what, at best, are statements applicable to particular fact situations," Schneller, 397 F.2d at 355, 158 USPQ at 215. Nonstatutory double patenting rejections based on Schneller will be rare. The Technology Center (TC) Director must approve any nonstatutory double patenting rejections based on Schneller. If an examiner determines that a double patenting rejection based on Schneller is appropriate in his or her application, the examiner should first consult with his or her supervisory patent examiner (SPE). If the SPE agrees

with the examiner then approval of the TC Director must be obtained before such a nonstatutory double patenting rejection can be made. MPEP §804(II)(B)(2) (emphasis added).

Indeed, Examiner's Note 1 of ¶8.39 explicitly states "This form paragraph should only be used where approval from the TC Director to make a nonstatutory double patenting rejection based on *In re Schneller* has been obtained." *MPEP §804*, ¶8.39, Examiner's Note 1. Applicant thus objects to the rejection of claims 1, 13, and 20 under ¶8.39 of MPEP §804.

Consistent with the rigorous requirements of MPEP §804 under ¶8.39, the section requires that to reject claims the "subject matter claimed in the instant application is <u>fully disclosed</u> in the referenced copending application." <u>MPEP §804</u>, ¶8.39. However, nowhere has the Examiner identified where, in copending Application 10/864,567, the claimed subject matter is <u>fully disclosed</u>. The Examiner has merely alleged that copending Application 10/864,567 discloses the claimed material but nowhere identified where such material is allegedly present or provided any supporting analysis.

Thus, nowhere has the Examiner alleged why the requirements for the use of ¶8.39 have been met, nor has the Examiner indicated where TC Director approval has been obtained.

In fact, not only does \$8.39 not apply, requirements for a double patenting rejection in general have not been met. MPEP \$804(II)(B)(I) states that, for an obviousness-type double patenting rejection (the section is specifically applicable to provisional rejections as well – See MPEP \$804(II) Header):

- Any obviousness-type double patenting rejection should make clear:
- (A) The differences between the inventions defined by the conflicting claims a claim in the patent compared to a claim in the application; and
- (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue >is anticipated by, or< would have been an obvious variation of >,< the invention defined in a claim in the patent. MPEP §804(II)(B)(1) (emphasis added).

The Examiner's reasoning has fallen well short of these requirements in provisionally rejecting claims 1, 13, and 20 on the ground of nonstatutory double patenting over claims 1, 8, and 16 of copending Application No. 10/864,567. Nowhere has the Examiner made clear the differences between the claims, and nowhere has the Examiner provided reasons why a person or ordinary skill in the art would conclude that the invention defined in the pending claims is anticipated by those in the copending Application No. 10/864,567.

In fact, Applicant believes the currently pending Double Patenting rejections are left substantively wanting, as well.

Claim 1 of the currently pending Application currently calls for a method of diagnostic imaging comprising the steps of acquiring a first set of TCT data from a first portion of a measurement surface using a TCT imaging device, determining a second set of TCT data from the first set of TCT data for a second portion of the measurement surface different from the first portion, and reconstructing an image of the imaging object, using the TCT imaging device, based on the first set and the second set of TCT data.

Conversely, claim 1 of copending Application No. 10/864,567 calls for a method of diagnostic imaging, the method comprising the steps of acquiring TCT data, determining an adjoint of the TCT data, determining a weighting operator, modifying the TCT data by the adjoint and the weighting operator to generate a reconstruction data set that avoids data truncation, and reconstructing an image of the subject from the reconstruction data set having reduced ghosting contributable to data truncation.

Clearly the claims themselves are of different scope, and a Double Patenting rejection is improper. A cursory review of claims 13 and 20 will, likewise, reveal that their rejections against respective claims 8 and 16 of copending Application No. 10/864,567 are equally lacking.

Thus, in summary, the double patenting rejections are wholly improper, as the conditions established in *In re Schneller* have not been met. Further, nowhere has the Examiner provided any evidence, indication, or even an allegation of TC Director approval. And, regardless, nowhere has the Examiner provided supporting analysis for the double patenting rejections. Indeed, nowhere do the claims, in fact, substantively meet the requirements of a double patenting rejection in general. Thus, Applicant requests the withdrawal of the provisional double patenting rejection of claims 1, 13, and 20 over claims 1, 8, and 16 of copending Application No. 10/864,567.

After the Double Patenting rejection, the Examiner included a "Response to Arguments" section. In that section, the Examiner provided some advice for the purpose of advancing prosecution. Office Action, 11/13/08, pg. 4. However, nowhere has the Examiner formally objected to the claims, and Applicant believes that the claims are clear and do not need amending for the purposes suggested by the Examiner. Indeed, Page 1 of the Office Action gives no indication that claims are objected to. If the claims are to be objected to, Applicant respectfully requests that an objection be included – to include the basis of the rejection as required in the MPEP. MPEP \$706.01.

Regarding claim 13, the Examiner first suggested amending the claim to call for "configured to" instead of "to." However, the Examiner did not make clear which "to" was being referred to. Claim 13 calls for, in part, an energy source <u>configure to...</u>, one or more sensors <u>configured to...</u>, and a computer <u>programmed to...</u> The claim is clear and needs no further amendments for any structural reasons identified by the Examiner.

Further, still regarding claim 13, the Examiner stated the "functional limitation regarding the computer is extremely broad and should be amended to include more specific steps..." Id. However, nowhere has the Examiner alleged that the claims are indefinite or unclear. In reviewing claims for patentability, nowhere does the MPEP require or even suggest that claims need to be amended because they are "extremely broad." Rather, the MPEP simply says that "[a]fter the application has been read and the claimed invention understood, a prior art search for the claimed invention is made." MPEP \$706. "With the results of the prior art search, including any references provided by the applicant, the patent application should be reviewed and analyzed in conjunction with the state of the prior art to determine whether the claims define a useful, novel, nonobvious, and enabled invention that has been clearly described in the specification." Id. In fact, nowhere does the MPEP allow or suggest that claims "should" be amended merely because they are "extremely broad." The rejection should be based solely on the prior art and, for this reason, Applicant declines the Examiner's requirement that the claim 13 "should" be amended for the sole reason that it is "extremely broad."

Regarding claim 1, the Examiner stated that "the term 'TCT data' is not specific enough and can include anything from echo signals to pixel intensities and anything therein between."

Office Action, 11/13/08, pg. 4. However, as with claim 13, nowhere has the Examiner formally objected to claim 1.

Further, regarding claim 1, the Examiner stated that "more specific steps regarding the determining of the second TCT data from the first TCT data should be included." However, as explained above, because no formal claim objection or allegation of indefiniteness has been expressed by the Examiner, Applicant declines to amend claim 1 as stated by the Examiner.

Claims 1, 13, and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger (USP 6,216,025) in view of Takashima (JP363211879). However, although Takashima (JP363211879) was the cited reference for these rejections, nowhere has the Examiner alleged what is taught or suggested by Takashima. Instead, the Examiner has cited Bae et al. in the rejections of claims 1, 13, and 24 and stated "Bae et al. teach extrapolating imaging data from acquired imaging data (para [00541)." Office Action, 11/13/08, pg. 6.

Thus, it is unclear which reference is being used to reject claims 1, 13, and 24. Applicant below addresses the Examiner's rejection in view of Bae et al. If Applicant is incorrect in this regard, Applicant respectfully submits that any subsequent Office Action cannot be made Final.

That called for in claim 1 is neither taught nor suggested in Kruger, Bae et al., or any combination thereof. In the rejections, the Examiner relied on Kruger for a number of claim elements, but then stated, "Kruger '025 may not explicitly teach creating a second TCT dataset by extrapolating data from the first TCT set." Id. The Examiner then relied on Bae et al. for allegedly teaching "extrapolating imaging data from acquired imaging data." Id. Thus, as in previous aspects of this file history, including a successfully argued Pre-Appeal Conference Request, the Examiner again is relying on Kruger for allegedly teaching the majority of claim elements in claim 1, and the Examiner is relying on Bae et al. for merely teaching "extrapolating imaging data from acquired imaging data." However, nowhere does Kruger teach or suggest that called for in claim 1 that is alleged by the Examiner.

Claim 1 calls for, in part, determining a second set of TCT data from the first set of TCT data for a second portion of the measurement surface different from the first portion.

Kruger teaches specific arrangements of multiple transducers on a rotatable imaging bowl for measuring acoustic waves produced in tissue when the tissue is exposed to electromagnetic radiation. Kruger, Abstract. Kruger describes acoustic shielding techniques to minimize stray echoes and sources of noise, techniques for cancelling noise, modulation of the time between imaging pulses to randomize the effect of acoustic echoes, and a filtering technique applied to compensate for the frequency response of the transducers. Id., Col. 3., Ins. 15-26. "The aim is to reconstruct some property of the breast from an ensemble of pressure measurements made externally to the breast." Id., Col. 10, Ins. 18-20. "An array of sixty-four acoustic transducers 33 is located within imaging bowl 14 in tank 16 [sic]." Id., Col. 6, Ins. 1-2. The transducers should be evenly spaced across the array, and are positioned in connection to Fig. 6. Id., Col. 6, Ins. 3-5.

Fig. 6 illustrates the positions of the transducers in the spiral array (some are shown in phantom). The position  $(r, 0, \Phi)$  as is illustrated in Fig. 6. Each of the N transducers 33 is on the spherical surface (at a constant radius R), located at a unique  $(0, \Phi)$  coordinate, and is oriented on the surface with its axis passing through the center C of the radium of curvature of the spherically curved surface of imaging bowl 14. The  $\Phi$  positions of the transducers 33 range from a minimum angle of  $\Phi_{min}$ , approximately 16.6 degrees, to a maximum angle of  $\Phi_{min}$ , approximately 72 degrees. It is desirable to maximize this range of angles, i.e., so that  $\Phi_{max} - \Phi_{min}$  is as large as possible, since doing so will enhance the extent to which features in the imaged tissue can be reconstructed in multiple dimensions. (In some embodiments,  $\Phi_{min} - \Phi_{min}$ ) the less than 45°;

however, in the embodiment of FIG. 6,  $\Phi_{max}$  - $\Phi_{min}$  approaches 90°.) *Id.*, Col. 9, Ins. 34-51.

Fig. 3 illustrates a pair of dome-shaped shells 31a and 31b having an air gap 32 formed between them, thus forming an acoustic barrier that is electromagnetically transparent. Id., Col. 7, Ins. 11-23. Fig. 5A illustrates details of analog data acquisition circuitry that is positioned near transducer 33 to maximize signal strength and improve noise immunity. Id., Col. 8, Ins. 27-31. Thus, Kruger teaches arrangements of transducers and techniques for measuring acoustic waves in tissue when the tissue is exposed to electromagnetic radiation. Nowhere does Kruger teach or suggest determining a second set of imaging data from a first set of data.

The Examiner alleged that the element "determining" or "deriving" a second TCT dataset from the first TCT dataset was present in Kruger. Office Action, 11/13/08, pg. 5. The Examiner stated, "Specifically, in order to plot the image, Kruger teaches acquiring a set of TCT data from one portion, storing the signals, then determining (based [sic] the first set of signals and any previous sets of signals) whether or not the data have been collected for all the sixty-four angular orientations of the imaging bowl. . . . 'Id. "If the data has not been collected for all the sixty-four angular orientations, then the imaging bowl is rotated 1/64 of a complete turn, positioning the transducers for the next set of signal measurements (Fig. 12B, step 114)." Id., pgs. 5-6. The Examiner errantly concluded, "This fully satisfies the language of 'acquiring' a first TCT set and then 'determining' or 'deriving' a second TCT set from the first TCT set." Id., pg. 6 (emphasis added).

However, it is in this last sentence where the Examiner's flawed logic is most evident. The Examiner is correct that data is first acquired and, if data has not been collected from all locations, the imaging bowl of Kruger rotates 1/64 of a turn for the next set of measurements. However, the next set of measurements are not obtained <u>from</u> the first set of data. Kruger merely teaches that additional data is obtained if the data at each angular position has not yet been obtained. Nowhere does Kruger teach or suggest obtaining a second set of data <u>from</u> a first set of data, as alleged by the Examiner.

Thus, nowhere does Kruger teach or suggest determining a second set of TCT data from a first set of TCT data as called for in claim 1. In fact, nowhere does Kruger make any reference to "deriving a second TCT dataset from the first TCT dataset."

In summary, not only does Kruger not teach or suggest determining a second set of TCT data from a first set of TCT data, it also does not teach deriving a second TCT dataset for a second portion of the measurement surface different from the first portion. The claim language is

clear. That is, claim 1 calls for determining a second set of TCT data <u>from</u> the first set of TCT data for a second portion of the measurement surface <u>different from</u> the first portion – and nowhere does Kruger teach or suggest these steps.

Bae et al. does not make up for the deficiency of Kruger. The Examiner stated, "Kruger '025 may not explicitly teach creating a second TCT dataset by extrapolating data from the first TCT set." Office Action, 11/13/08, pg. 6. The Examiner further stated that "in the field of tissue imaging and reconstruction, Bae et al. teach extrapolating imaging data from acquired imaging data (para [0054])." Id. However, nowhere does Bae et al. teach or suggest creating a second TCT dataset from a first TCT dataset.

Bae et al. is directed toward CT imaging and at the cited location, Bae et al. teaches that "[flhe preferred slice thickness and reconstruction interval for the CT slices is 1 mm or less," but the algorithm disclosed therein can accommodate different slice thicknesses and reconstruction intervals. Bae et al., Para. [0054]. "After the boundary of the lung region is refined as described above in connection with FIG. 2, the 2D segmented lung regions can be stacked to generate a 3D volumetric data set of the lung region." Id. "If the reconstruction interval is larger than 1 mm, finer-resolution slices can be interpolated at every 1 mm using the slice neighboring above and the slice neighboring below and integrated into the expanded 3D volumetric dataset." Id.

Thus, Bae et al. teaches interpolation of CT data. Incidentally, the Examiner alleged that Bae et al. teaches <u>extrapolating</u> data at the cited location. However, as is clearly evident from the citations above, nowhere does Bae et al. suggest anything to do with extrapolation of data. And, regardless of that interpretation, nowhere does Bae et al. make up for the deficiency of Kruger regarding the rejection of claim 1. Thus, nowhere does Kruger, Bae et al., or a combination thereof teach or suggest the claimed subject matter.

As stated, claim 1 calls for determining a second set of TCT data from the first set of TCT data. However, claim 1 further calls for determining the second set for a second portion of the measurement surface different from the first portion. Thus, although Bae et al. may teach interpolation of data, neither reference alone or in combination teaches or suggests determining the second set for a second portion of the measurement surface different from the first portion.

Thus, that called for in claim 1 is neither taught nor suggested by Kruger, Bae et al., or a combination thereof.

Claims 13 and 24 have been amended. Claim 13 calls for, in part, a TCT imaging system having a computer programmed to derive, from acquired data, unacquired data for an imaging object for positions where no sensor has been placed. Claim 24 calls for, in part, generating a

first TCT dataset from the ultrasonic emissions and deriving a second TCT dataset from the first TCT dataset, the second TCT dataset including data for sensor positions not included when obtaining the first dataset.

Nowhere does Kruger, Bae et al., or a combination thereof teach or suggest the claimed subject matter. Neither reference, alone or in combination, teaches or suggests deriving unacquired data for an imaging object for positions where no sensor has been placed, as called for in claim 13. Neither reference, alone or in combination, teaches or suggests deriving a second TCT dataset from the first TCT dataset, the second TCT dataset including data for sensor positions not included when obtaining the first dataset as called for in claim 24.

As such, Applicant believes that which is called for in claims 1, 13, and 24 is not taught or suggested by Kruger and requests allowance thereof. In light of claims 2, 4-12, 14-19, and 25-26 depending from what are believed otherwise allowable claims, Applicant requests allowance of claims 2, 4-12, 14-19, and 25-26 based on the chain of dependency.

Claims 13 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger in view of Bae et al., further in view of Ben-Haim et al. In the rejections, the Examiner stated that Kruger and Bae et al. teach the limitations as discussed, but that "Kruger '025 does not teach using a TCT data set to determine a second set of TCT data through the use of a Legendre Polynomial." Office Action, 11/13/08, pg. 7.

Before addressing the substance of the rejections, Applicant first points out the inconsistencies in the rejection of claim 13. The rejection of claim 13 was based on 35 U.S.C. \( \) \(

Claim 13 has been amended and is discussed above. Claim 20 calls for, in part, acquisition of TCT data from an imaging object, and determination of TCT data corresponding to a desirable transducer location about the imaging object not having a transducer location. Neither reference, alone or in combination, teaches or suggests that called for in claims 13 and 20.

Ben-Haim teaches a locating system for determining the location and orientation of an invasive medical instrument relative to a reference frame. Ben-Haim, Abstract. The position and

orientation of a distal end of a catheter are ascertained by use of two or three antennas, such as radiators 18, 20, and 22. Id., Par. 103. The three radiators are driven by a radiator driver 24 and, along with a signal processor 26, provide "a display or other indication of the position and orientation of the distal end 15 on a monitor 27," Id., Par. 105. "[T]he field equations are derived specifically for each embodiment and are dependent on the geometry and characteristics of the radiators," Id., Par. 147. In the preferred embodiment where the radiators are coils, for a coil with N turns, radius R, and current I, a series of vector equations are generated wherein a radial and tangential component are described. Id., Pars. 147-148. The tangential component includes an expression, P<sub>n</sub>(x), which is a Legendre Polynomial of degree n which may be calculated recursively through the method described. Id., Pars. 149-153. Thus, the field sensed by a remote sensor results in equations having known and unknown variables for any given coil. Id., Pars, 154-155. In the embodiment having three sensors, the technique described results in an overdetermined series of nine equations and six variables and, with nine sensor readings, the unknowns may be numerically solved for by using, for instance, a Newton-Raphson method for non-linear systems, and "Ithe location sensor position and orientation are displayed on monitor 27." Id., Pars. 158-159.

Thus, Ben-Haim describes obtaining a location and orientation of an invasive medical instrument using a numerical solution that includes a Legendre Polynomial.

Nowhere does Kruger, Bae et al., Ben-Haim or a combination thereof teach or suggest deriving unacquired data for an imaging object for positions where no sensor has been placed, as called for in claim 13. Neither reference, alone or in combination, teaches or suggests acquiring TCT data from the imaging object and, from the coefficients, determining TCT data corresponding to a desirable transducer location about the imaging object not having a transducer location as called for in claim 20.

Accordingly, that which is called for in claims 13 and 20 is not taught or suggested by Kruger, Bae et al. Ben-Haim, or a combination thereof. In light of claims 14-19, and 21-23 depending from what are believed otherwise allowable claims, Applicant requests allowance of claims 14-19, and 21-23 based on the chain of dependency.

Therefore, in light of at least the foregoing, Applicant respectfully believes that the present application is in condition for allowance. As a result, Applicant respectfully requests timely issuance of a Notice of Allowance for claims 1, 2, and 4-26.

Applicant appreciates the Examiner's consideration of these Amendments and Remarks and cordially invites the Examiner to call the undersigned, should the Examiner consider any matters unresolved.

Respectfully submitted,

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Dated: January 13, 2009 Attorney Docket No.: GEMS8081.195

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## General Authorization and Extension of Time

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 07-0845. Should no proper payment be enclosed herewith, as by credit card authorization being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 07-0845. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extensions under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 07-0845. Please consider this a general authorization to charge any fee that is due in this case, if not otherwise timely paid, to Deposit Account No. 07-0845.

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